IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

IN RE NORPLANT CONTRACEPTIVE PRODUCTS LIABILITY LITIGATION	:	**MDL DOCKET NO. 1038**
	:	**ALL CASES**

No. 1

MEMORANDUM IN SUPPORT OF
MOTION FOR PARTIAL SUMMARY JUDGMENT
RE THE LEARNED INTERMEDIARY DOCTRINE/CAUSATION

INTRODUCTION

In August 1996, the Court put in place a plan to conduct three back-to-back trials, each of which would resolve the claims of five bellwether plaintiffs. *Memorandum Opinion and Order Denying Plaintiffs' Motion for Class Certification and Dismissing Class Complaint* (August 6, 1996). What the Court could not have anticipated at the time, but has proven true, is that the first trial would provide all the "bellwether" guidance the Plaintiffs' Steering Committee would want or need. This Court granted summary judgment in favor of Wyeth on the ground that the Learned Intermediary Doctrine governed each of plaintiffs' failure-to-warn claims, however pled, and that the five plaintiffs had failed to demonstrate that any alleged inadequacy in the Norplant warnings to their physicians was a producing cause of their claimed injuries. *In re Norplant Contraceptive Products Liability Litigation*, 955 F. Supp. 700, 710-11 (E.D. Tex. 1997), *aff'd*, 165 F.3d 374 (5th Cir. 1999). The cornerstone of the Court's decision was the consistent testimony of the five prescribing physicians that they were "fully aware of the potential side effects alleged by the plaintiffs and the severity of those side effects before prescribing Norplant." *Id.* at 710.

The second and third bellwether trials, of course, never happened. Upon granting summary judgment, the Court invited counsel to schedule the second trial. Uncharacteristically for a group of plaintiffs, but tellingly, the Steering Committee asked for time to consider whether it wanted a second trial, then asked for more time, then declined the offer. The reason for that strategic decision is apparent: the Steering Committee recognized that, if the Learned Intermediary Doctrine governed plaintiffs' claims, they would lose, for ***every*** health care provider could be expected to provide the same testimony as the prescribing physicians for the first five bellwether plaintiffs. Put differently, the Steering Committee recognized that plaintiffs could not win on the facts; they could only win by securing a change in the law (or by forum-shopping for judges who would not apply the law).

First, then, plaintiffs appealed this Court's summary judgment ruling, asking the Fifth Circuit to recognize a "contraceptive exception" to the Learned Intermediary Doctrine.[1] The Fifth Circuit declined to do so, affirming this Court's ruling. 165 F.3d 374 (5th Cir. 1999). Plaintiffs have not returned to this Court to request that the second and third groups of bellwether plaintiffs be set for trial. Instead, plaintiffs' counsel turned their attention to state Norplant cases, hoping for a different outcome.

The Steering Committee was right: in the four-year course of the Norplant litigation, some 33 health care providers who either counseled about or prescribed Norplant have

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[1] Plaintiffs in the Indiana consolidated Norplant litigation reached the same conclusion as the Steering Committee. Plainly believing that, absent recognition of a "contraceptive exception" to the Learned Intermediary Doctrine, they would meet the same fate as the MDL bellwether plaintiffs, the Indiana plaintiffs preemptively moved for "partial summary judgment" on the abstract question of whether Indiana applies the Learned Intermediary Doctrine. The Indiana court denied plaintiffs' motion, holding that the doctrine applies to Norplant; the Indiana Court of Appeals refused to entertain an interlocutory appeal; and the Indiana plaintiffs have never since sought to bring a case to trial.

testified by affidavit, by deposition, or at trial.[2] To a person, each has affirmed that he or she knew, before prescribing Norplant, that the common adverse reactions listed in the Norplant Prescribing Information were possible side effects associated with Norplant use.[3] This consistent testimony is not a coincidence. As Dr. Anita Nelson explains in support of this motion, the testimony reflects the simple, expected fact that every medical professional whose regular practice includes contraceptive counseling knows the common side effects of Norplant (and other progestin-containing contraceptives). Unless an individual plaintiff can come forward with evidence that her physician knew differently, partial summary judgment should be granted as to all of that plaintiff's claims that Wyeth failed to warn about the listed "Adverse Reactions."

THE UNDISPUTED EVIDENCE

The Norplant System is one of the most extensively studied contraceptive products ever to be marketed in the United States. Norplant was the subject of nearly twenty years of research, development, and clinical testing conducted by the Population Council, a non-

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2 Several of these healthcare providers treated women who were hand-picked by plaintiffs' counsel to serve as trial plaintiffs in test cases.

3 This motion is limited to the 26 side effects specifically listed as "Adverse Reactions" in the Norplant Prescribing Information. Tab 36. The MDL plaintiffs collectively allege side effects numbering in the hundreds. But as the co-chairman of the Plaintiffs' Steering Committee explained at a conference in chambers:

> So, instead of the fifty that we laid out in our complaint, we now see that by their own studies, there were only a dozen core complaints . . . .
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> * * *
>
> We are going to resolve over ninety percent of these cases by a trial that determines their failure to warn adequately about nine symptoms, nine adverse reactions.

May 14, 1996 Informal Conference, at 21, 23, Tab 56. This motion therefore stands to resolve the primary claims in the majority of pending cases.

profit research organization devoted to developing and preserving contraceptive options. Affidavit of Margaret E. Weber, M.D., ¶¶ 3, 4 ("Weber Aff."), Tab 32; Affidavit of Stephen F. Heartwell, Dr.P.H., ¶ 9 ("Heartwell Aff."), Tab 33. The voluminous clinical data generated by the Norplant clinical trials formed the basis for the December 1990 Food and Drug Administration approval of the product and its labeling. Heartwell Aff., ¶ 4. A copy of the FDA-approved Physician and Patient Labeling is included in every Norplant System kit sold in the United States. Weber Aff., ¶ 5.

Norplant has been the subject of literally hundreds of peer-reviewed articles published in the medical and scientific literature in the last three decades. Even before the 1990 FDA approval of Norplant, more than 300 articles about the product had been published. Tab 39; Affidavit of Anita Nelson, M.D., ¶ 18 ("Nelson Aff."), Tab 34. Following approval, at least another 660 scientific articles appeared in the literature. Tab 40. Norplant continues to be the subject of research and evaluation even today. New articles about the contraceptive appear regularly in the scientific literature (at least 120 in 1998 alone).

Following FDA approval of Norplant, Wyeth developed and implemented an extensive training program designed to familiarize health care practitioners with the constituent elements of Norplant, the clinical trial data on which the product labeling is based, the potential side effects associated with Norplant use, and the correct insertion and removal of the product. Nelson Aff., ¶¶ 9, 10. Since 1990, nearly one million women have used Norplant under the care of their health care providers. Nelson Aff., ¶ 18; Weber Aff., ¶ 7. During the four-year course of the Norplant litigation, 33 of those health care providers have testified about their experiences with contraceptive counseling generally, hormonal contraceptives specifically, and Norplant in particular. Their testimony reflects the unsurprising fact that every health care provider whose

regular practice includes counseling about and prescribing hormonal contraceptives is familiar with the common side effects of Norplant (and other progestin-containing contraceptives). This body of testimony is consistent, significant, and entirely uncontradicted.

These undisputed facts form the predicate for the affidavit of Anita Nelson, M.D., a board-certified obstetrician-gynecologist and Associate Professor of Obstetrics and Gynecology at the UCLA School of Medicine. Dr. Nelson participated in one of the earliest Norplant provider training programs in January 1991 and has, over the last eight years, had extensive contact with medical professionals across the country who have inquired about, been trained in the use of, and/or prescribed Norplant. She has trained hundreds of health care providers in the proper insertion, removal, counseling, and use of Norplant. Nelson Aff., ¶¶ 11, 13. She has spoken to physicians who have called the Norplant advice line. She has extensive clinical experience with Norplant, having inserted and/or removed several hundred Norplant Systems herself. *Id.* at ¶ 14. And she is familiar with the extensive medical literature on Norplant and the counseling and training materials prepared by Wyeth. Based on her broad experience with Norplant and with the medical professionals who use it, Dr. Nelson concludes that "any obstetrician-gynecologist, family practitioner, or other health care provider who as a part of his/her regular practice counsels women about contraception would be familiar with the 26 side effects described as Adverse Reactions in the [Norplant] physician labeling." *Id.* at ¶ 19. For that reason, it comes as no surprise to her that the doctors have testified as they have: "I would expect every medical professional whose regular practice included contraception counseling to testify to the same effect." *Id.* at ¶ 23.

ARGUMENT

I. THE LEARNED INTERMEDIARY DOCTRINE GOVERNS PLAINTIFFS' FAILURE-TO-WARN CLAIMS.

The law governing plaintiffs' failure-to-warn claims is settled: the Learned Intermediary Doctrine defines Wyeth's duty to warn of the potential risks associated with the use of Norplant. This Court has so held, *In re Norplant Contraceptive Products Liability Litigation*, 955 F. Supp. 700, 703-09 (E.D. Tex. 1997), and the Fifth Circuit has affirmed, 165 F.3d 374 (5th Cir. 1999). The vast majority of states – at least 45 in number[4] – apply the Doctrine to define a pharmaceutical company's duty to warn of risks associated with use of a prescription drug. The drug company's duty, as established by the Doctrine, is to warn prescribing health care providers of the side effects associated with use of a prescription drug. *In re Norplant*, 955 F. Supp. at 703. The provision of a proper warning to the health care provider fully satisfies the drug company's duty to warn. *Id.*

As this Court has recognized, courts nationwide routinely apply the Doctrine to prescription contraceptives just as they do to other prescription drugs. *Id.* at 704 & n. 18 (citing 28 cases from 22 jurisdictions). With a single exception, every state to have considered the question has rejected plaintiffs' entreaties to carve out a "contraceptive exception" to the Learned Intermediary Doctrine. Massachusetts alone recognized such an exception over a decade ago, *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65 (Mass. 1985), but this Court rejected the *MacDonald* "active patient/passive physician" rationale, *In re Norplant*, 955

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[4] Attached at Tab 41 is a table reflecting the decisions of the various jurisdictions that have recognized the Learned Intermediary Doctrine.

F. Supp. at 707, and no state court has adopted it in the 14 years since *MacDonald* was decided.[5] In the Norplant litigation specifically, six courts, this Court included, have applied the Learned Intermediary Doctrine to grant summary judgment to Wyeth. *See* Tabs 6, 10, 12-14, 19.

In short, then, "there is no principled distinction to be drawn between prescription contraceptives and other prescription drugs insofar as application of the Learned Intermediary Doctrine is concerned." *In re Norplant*, 955 F. Supp. at 707. It applies to every one of plaintiffs' failure-to-warn claims, however pled, and obligates Wyeth to provide an adequate warning to prescribing health care providers alone.

II. ABSENT PROOF THAT A DEFICIENCY IN THE NORPLANT WARNINGS CAUSED THEIR ALLEGED INJURIES, PLAINTIFFS CANNOT PREVAIL.

A. It Is Plaintiffs' Burden to Establish That Their Health Care Providers Were Unaware of Norplant's Side Effects Before Prescribing the Product.

It is plaintiffs' burden to show, not only that Wyeth furnished health care providers with an inadequate warning about the potential side effects associated with Norplant use, but that "a different warning would have changed the decision of the treating physicians." *In re Norplant*, 955 F. Supp. at 711; *see also, e.g., Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex. App.—Waco 1993, writ denied). To prove that the allegedly deficient warning was a proximate or producing cause of her injuries, a plaintiff "must show that a proper warning would have changed the decision of the treating physician, *i.e.*, that but for the

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[5] Indeed, even one Massachusetts court has subsequently rejected application of the *MacDonald* exception in a case involving an IUD. *Raimer v. G.D. Searle*, Civ. No. 870248 (Mass. Super. Ct. Jan . 31, 1991), Tab 99. In *Raimer*, the trial court granted summary judgment to Searle on plaintiffs' failure to warn and breach of contract claims, finding that the health care provider's role in prescribing an IUD was an active one (in that a health care provider must insert and remove the contraceptive device), and therefore applying the Learned Intermediary Doctrine. The same rationale supports application of the Doctrine to cases involving Norplant, which similarly must be inserted and removed by the health care provider.

inadequate warning, the treating physician would not have used or prescribed the product." *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1098-99 (5th Cir. 1991). Put differently, when the prescribing physician was aware of the possible side effects of a drug, "yet chose to use it regardless of the adequacy of the warning, then, as a matter of law, the adequacy of the warning was not a producing cause of [plaintiff's] injury." *Stewart v. Janssen Pharmaceutica, Inc.*, 780 S.W.2d 910, 912 (Tex. App.—El Paso 1989, writ denied).[6]

With regard to the 26 side effects listed in the Adverse Reactions section of the Norplant Prescribing Information, every MDL plaintiff's case fails on the element of causation – absent proof that her prescribing physician was unaware of those commonly complained-about side effects before prescribing Norplant. Dr. Nelson's testimony demonstrates that plaintiffs cannot present such proof. Nelson Aff., ¶ 19, Tab 34. And the consistent testimony of the medical professionals whose patients have been selected as trial plaintiffs confirms the truth of her opinion. It is appropriate and timely to put plaintiffs to their burden of proof on this issue. On motion for summary judgment, "a complete failure of proof concerning an essential element of [plaintiffs'] case necessarily renders all other facts immaterial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986) (upholding district court's grant of summary judgment to defendant where plaintiff produced no evidence that her injuries were caused by defendant's asbestos product). Proof of causation is indisputably an "essential element" of each plaintiff's case. Therefore, if each plaintiff cannot produce evidence that her prescribing physician was unaware of Norplant's listed "Adverse Reactions," Wyeth is entitled to partial summary judgment against

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6 Similarly, when the prescribing physician, even if unaware of certain information, would still have prescribed the drug had that information been included in the physician labeling, then again, as a matter of law, the alleged inadequacy of the warning was not a cause of the plaintiff's injury. *See, e.g., Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 817 (5th Cir. 1992) (affirming grant of judgment n.o.v.); *Willett*, 929 F.2d at 1099 (affirming grant of summary judgment).

her as to all such claims. After four years of litigation, the undisputed evidence suggests that plaintiffs cannot meet their burden.

B. All Health Care Providers Who Counsel About and Prescribe Hormonal Contraceptives as a Part of Their Regular Medical Practice Can Be Expected to Testify That They Knew the Side Effects of Norplant Before Prescribing It.

Dr. Anita Nelson has had unusually broad experience with Norplant and extensive dealings, nationally and internationally, with doctors who use it. Nelson Aff., ¶¶ 11, 13, 14, Tab 34. Given (i) the training offered to medical professionals using Norplant, (ii) the counseling materials provided to them, (iii) the voluminous medical literature about Norplant, (iv) the long-term experience of doctors with levonorgestrel, and (v) their general awareness of the side effects of progestin-containing contraceptives, Dr. Nelson concludes that "***any obstetrician-gynecologist, family practitioner, or other health care provider who as a part of his/her regular practice counsels women about contraception would be familiar with the 26 side effects described as Adverse Reactions in the [Norplant] physician labeling***." Nelson Aff., ¶ 19 (emphasis supplied).

The evidence underlying Dr. Nelson's conclusion is not subject to dispute. To begin with, the FDA-approved Norplant physician labeling is prominently displayed in each Norplant System kit. The "Adverse Events" section of the physician labeling lists the side effects that are possibly, probably, or known to be associated with Norplant use based on the data from the Norplant clinical trials. A health care provider planning to prescribe and insert Norplant cannot open the Norplant System package without seeing the physician labeling.

The potential adverse reactions included in the Norplant labeling did not come as a surprise to physicians. The synthetic hormone levonorgestrel, the sole active ingredient in Norplant, had been used in oral contraceptives in the United States for more than 25 years by the

time of Norplant approval and had been the subject of countless articles in the medical literature. By 1990, therefore, health care providers were familiar with levonorgestrel's side effect profile, which is common to all progestin-containing methods. Nelson Aff., ¶ 17.

Moreover, before the FDA approved Norplant, it was the subject of clinical trials and pre-introductory studies spanning 20 years. Information gleaned from trials and studies was reported in over 300 articles in the published medical and scientific literature even before the 1990 FDA approval. Nelson Aff., ¶ 18. Another 660 articles were published following FDA approval, Tab 40, and data collected from post-approval studies continues to appear in the medical literature even today. This body of literature not only familiarized practitioners with the side effects associated with Norplant use before it was introduced in the United States, but also confirmed the results of the Norplant clinical trials as reflected in the "Adverse Reactions" section of the Norplant labeling. Nelson Aff., ¶ 18.

As the first significant contraceptive innovation in decades, Norplant was also the topic of both formal discussion in continuing medical education settings and informal discussion among health care practitioners who counsel women about contraceptive options. Dr. Nelson, for example, both attended and conducted Norplant training courses, handled inquiries to the Norplant advice line, spoke to users, and conferred with providers in China who had inserted thousands of sets. Nelson Aff., ¶¶ 10, 11, 13, 15. At every turn, she has found that the side effects reported by Norplant users and observed by their health care providers are precisely those listed in the Norplant Prescribing Information. Nelson Aff., ¶ 15.

C. The Health Care Providers Who Have Testified in the Norplant Litigation Have Affirmed That They Were Familiar With the Side Effect Profile Before Prescribing Norplant.

Based on the basic knowledge possessed by every medical professional whose regular practice involves contraceptive counseling, Dr. Nelson "would expect every [such] medical professional . . . to testify" that they knew of Norplant's common side effects before prescribing it. Nelson Aff., ¶ 23. And indeed, ***every*** health care provider who has testified in the Norplant litigation, from the first providers deposed in the MDL to the most recent provider to submit a sworn affidavit in state-court litigation, has made clear that they were aware before prescribing the drug of the potential side effects associated with Norplant, as listed in the Adverse Reactions section of the physician labeling. In other words, not a single plaintiff to date has been able to establish that her health care provider was unaware of the potential side effects listed in the physician labeling.

Dr. Melvin Bottorff, a board-certified obstetrician-gynecologist who prescribed Norplant for Theresa Goins (an MDL bellwether plaintiff), was one of the first health care providers to testify in the Norplant litigation. Dr. Bottorff testified that he was aware of Norplant's possible side effects before prescribing it for Ms. Goins (including the possibility that she could experience more than one side effect and that the severity could range from mild to severe). Notwithstanding plaintiffs' counsel's attempts to change his mind, he testified that he continues to believe that Norplant was an appropriate choice for Ms. Goins:

> Q. Now, I just want to make clear about the type of side effects that you as a physician were aware of. Would you please tell me as to each one of these side effects were you aware of these before you prescribed the Norplant—that these were possible side effects that a woman could experience, okay?
>
> A. Okay.

Q. Severe headaches, mood swings, depression, nausea, acne, arm pain, numbness . . . breast tenderness, weight gain, hair loss, cramps, bleeding irregularities including amenorrhea . . . were you aware that those were possible side effects that a woman could experience?

A. Yes.

Q. And you were aware that she could have more than one of these side effects?

A. Yes.

* * *

Q. [W]ould it be fair to say, Doctor, that you knew in advance that different degrees of nausea, for example; different degrees of headaches; different degrees of bleeding problems—that those types of things could be experienced in different ways by different women?

A. Yes.

* * *

Q. [D]o you still consider Norplant to be a safe and effective product generally?

A. Yes.

Q. And do you consider it specifically to have been a safe and effective product for Theresa Goins?

A. Yes.

Deposition of Melvin Bottorff at 34-35, 119-20, 127-28, Tab 60.

Dr. Dallas Coate, a board-certified family practice physician who has prescribed Norplant for more than 50 women and is the most recent physician to testify in the litigation, holds the same view. In an affidavit submitted in support of Wyeth's summary judgment motion in the Indiana bellwether case, Dr. Coate stated that he was fully aware of Norplant's potential side effects before prescribing it for his patients:

> After reading the labeling, I clearly understood that menstrual irregularities were the most common side effect associated with Norplant as a progestin-only contraceptive. I also understood that the various side effects associated with Norplant could occur with varying frequency and severity. . . . I also understood that a patient could experience one side effect or several side effects at the same time. My understanding of these was based not only on my reading of the Norplant labeling but also on my knowledge of drugs and contraceptives in general and progestin-only contraceptives in particular.
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> There are many ways to describe menstrual irregularities and other side effects associated with Norplant. A different description in the labeling would not have been helpful or changed my decision to prescribe Norplant.
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> * * *
>
> When I inserted Norplant for Ms. Pucillo, I believed it to be a safe, effective, and appropriate contraceptive method for her. Based on everything I know about Norplant today, I continue to hold that belief and continue to prescribe Norplant to patients seeking long-term contraception. *Because I know [sic] when I prescribed Norplant for Ms. Pucillo that the side effects she complained of were possible risks of using that form of contraception, I would weigh the benefits and risks of using Norplant the same today as when I prescribed it in 1993. . . .*

Affidavit of Dallas E. Coate, M.D., ¶¶ 6-7, 12-13, Tab 61.[7]

The testimony of virtually every other health care provider who has testified in the Norplant litigation is to similar effect. All told, 33 providers who either counseled about or prescribed Norplant have testified in the Norplant litigation:

- Five physicians testified in the first MDL bellwether proceeding: Drs. Bottorff, Haman, Brown, Balsley, and Hollins. All five agreed that they were aware, before prescribing Norplant for the five bellwether plaintiffs, that the side effects the plaintiffs claimed were potential risks of Norplant use. Tabs 60, 62-65. On the basis of that undisputed testimony, this Court granted summary judgment in favor of Wyeth.

- In the first Norplant case to go to trial (Hidalgo County), seven health care providers (Drs. Martinez, Breen, Cantu, Garcia, and Zapata and Nurse Practitioners Keyes and

[7] Not only did plaintiff Pucillo not contest the affidavit, she ***conceded*** Wyeth's motion for summary judgment based on the Learned Intermediary Doctrine.

Ellis) testified uniformly in depositions that they were aware of the side effects associated with Norplant use prior to prescribing it for the plaintiffs. Tabs 66-72. Their testimony was never presented to a jury, because plaintiffs' counsel sought and was granted a mistrial.

- In the first Norplant case to be tried to verdict (Cameron County), plaintiff Maria Valles' inserting health care provider, Certified Nurse Midwife Beth-Michele Wargo, testified that she was aware of the possibility of each of the side effects claimed by Ms. Valles before prescribing Norplant for her. Tab 73. The jury returned a verdict in favor of Wyeth.

- In the Alabama bellwether cases, Dr. Timothy Marlow, who prescribed Norplant for approximately 700 patients, testified that he was aware of the common side effects of Norplant before prescribing it for his patients. Tab 74.

- In the Norplant litigation in Harris County, three health care providers (Drs. Ritter, Devine, and Obukofe) submitted sworn affidavits attesting that they were each aware, before prescribing Norplant, that the side effects listed in the Norplant labeling were possible risks of using the product. In response to Wyeth's summary judgment motion, three plaintiffs filed non-suits. The court granted summary judgment against the one plaintiff who did not non-suit. Tabs 75-77.

- In the consolidated Norplant litigation in New Jersey, six health care professionals (Drs. Carlson, Shah, Chuback, and Sinofsky; family planning counselor Leda Munoz, and Nurse Practitioner Diane Brevet) testified that they were aware of the possible side effects of Norplant as set forth in the Prescribing Information. Tabs 78-82.

- Nine providers (Drs. Stutes, DeWet, Kirk, Price, Tatum, Gluck, and Coomansingh; Nurse Practitioner Bonnie George; and licensed social worker/family planning director Connie Jackson) testified to the same effect in the Norplant litigation in Jefferson County: Each made clear that he or she was familiar with the potential side effects of Norplant use as set forth in the Norplant labeling. Tabs 83-91.

In sum, ***not a single physician or nurse practitioner has testified that he or she was unaware of the side effects associated with Norplant or that he or she would have made a different prescribing decision had the Norplant warnings been altered***. That consistency is all the more telling because Wyeth did not hand-pick the medical professionals who testified. They were simply the prescribing providers and/or counselors for trial plaintiffs who either emerged from selection procedures like that put in place by this Court for the first bellwether trial or who

were hand-picked by plaintiffs' counsel. There is no reason to expect that any other health care provider would testify differently.

CONCLUSION

The undisputed testimony submitted in support of this motion establishes that plaintiffs cannot prove that each of their prescribing physicians was unaware of the possible side effects listed as "Adverse Reactions" in the Norplant physician labeling. If each plaintiff cannot come forward with such proof now, partial summary judgment is in order as to ***all*** plaintiffs on ***all*** failure-to-warn claims regarding the listed "Adverse Reactions."

Respectfully submitted,

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